



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory
Services

4700 River Road
Riverdale, MD
20737

Dr. Patrick Schnable
2035B Roy J Carver Co-Lab
1111 WOI Rd
Iowa State University
Ames, IA 50011-3650

Re: Confirmation of Regulatory Status of Null Segregant Maize Lines

Dear Dr. Patrick Schnable,

Thank you for your letter dated April 20, 2018, inquiring whether the maize (*Zea mays*) product described in your letter is a regulated article under 7 CFR part 340. Your letter describes two maize null segregant progeny plants, #4 and #6, not containing any transgenes, both of which were derived from a parental transgenic plant. The resulting desired phenotype is claimed as CBI.

The Plant Protection Act (PPA) of 2000 gives USDA the authority to oversee the detection, control, eradication, suppression, prevention, or retardation of the spread of plant pests or noxious weeds to protect the agriculture, environment, and economy of the United States.

USDA regulates the importation, interstate movement and environmental release (field testing) of certain genetically engineered (GE) organisms that are, or have the potential to be, plant pests. Regulations for GE organisms that are or have the potential to be plant pests, under the PPA, are codified at 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests." Under the provisions of these regulations, a GE organism is deemed a regulated article if it has been genetically engineered using a donor organism, recipient organism, or vector or vector agent that is listed in §340.2 and meets the definition of a plant pest, or that is an unclassified organism and/or an organism whose classification is unknown, or if the Administrator determines that the GE organism is a plant pest or has reason to believe it is a plant pest.

In your April 20, 2018 letter, you described that a plasmid containing T-DNA was inserted into maize inbred line B104. This T-DNA contained gRNAs targeting a gene in the maize genome for genome editing in order to study the function of this particular gene. You stated that the plasmid system containing the Cas9 gene was delivered to your maize variety via *Agrobacterium tumefaciens* and that plant pest sequences were used in the plasmid as regulatory elements. You further stated in your letter that from the parental transgenic plant you obtained two null segregants (#4 and #6) having a single base-pair (bp) insertion and a 50bp deletion and they were the subject of your inquiry. The maize lines #4 and #6 were subjected to PCR analysis using 28 PCR primer pairs covering the entire T-DNA construct to confirm that the maize lines do not contain the transgenes or any plant pest sequences used during transformation.

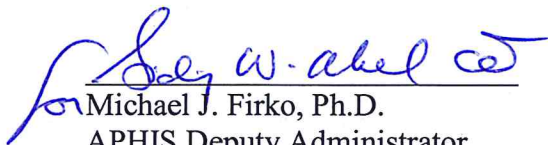
Based on the information you provided in your April 20, 2018 letter, USDA has determined that the described genome-edited maize lines #4 and #6 are not themselves plant pests and they do not contain any plant pest sequences or any other inserted genetic material. The only genetic changes in the genome-edited maize lines #4 and #6 are the single nucleotide insertion and a 50bp deletion. Since no DNA repair template was provided, the resulting insertion and deletion were produced by the plant's own naturally-occurring DNA repair mechanism. Therefore, consistent with previous responses to similar letters of inquiry, USDA does not consider the maize (*Zea mays*) lines #4 and #6 as described in your April 20, 2018 letter to be regulated pursuant to 7 CFR part 340. Additionally, maize is not listed as a Federal noxious weed pursuant to 7 CFR part 360, and USDA has no reason to believe that the introduced phenotype in maize lines #4 and #6 would increase the weediness of maize.

Please be advised that the importation of maize seeds or plants, like all other maize, will be subject to Plant Protection and Quarantine (PPQ), permit and/or quarantine requirements. For further information, should you plan to import these maize seeds or plants, you may contact the PPQ general number for such inquiries at (877) 770-5990.

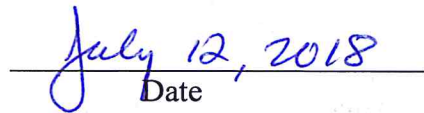
Please be advised that your maize, while not regulated by USDA under 7 CFR part 340 may still be subject to other regulatory authorities such as FDA or EPA.

Should you become aware at any time of any issues that may affect the Agency's conclusion regarding this inquiry, you must immediately notify the Agency in writing of the nature of the issue. We hope that you appreciate our commitment to plant health and support for the responsible stewardship for the introduction of GE plants.

Sincerely,


Michael J. Firko, Ph.D.

APHIS Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture


Date